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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/608,899	06/27/2003	Lisa M. Donnelly	022956-0218	7787
21125	7590	09/06/2006	EXAMINER	
NUTTER MCCLENNEN & FISH LLP WORLD TRADE CENTER WEST 155 SEAPORT BOULEVARD BOSTON, MA 02210-2604			BLANCO, JAVIER G	
		ART UNIT	PAPER NUMBER	3738

DATE MAILED: 09/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/608,899	DONNELLY ET AL.
	Examiner	Art Unit
	Javier G. Blanco	3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 22 June 2006.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-9, 11-17, 20 and 21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-9, 11-17, 20, and 21 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>7/7/2006</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicants' submission filed on June 22, 2006 has been entered.

Response to Amendment

2. Applicants' amendment of claims 1, 2, 11, and 12 in the reply filed on June 1, 2006 is acknowledged.
3. Applicants' addition of claims 20 and 21 in the reply filed on June 1, 2006 is acknowledged.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1, 2, 5-7, and 11-17 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Kim (US 2002/0007182 A1; cited in Applicants' IDS).

Referring to Figures 1-8, 13, and 17, Kim discloses a graft fixation device comprising: (i) a bioabsorbable (see paragraphs 0040, 0050) radially expandable sheath (anchor 10) having a slot-free distal tip (rounded tip/point 12) with at least two sidewalls (legs/wings 18, 20) extending proximally therefrom and defining a central lumen (eye/aperture 22, opening 16, and/or lumen/space between legs/wings 18, 20), each sidewall having a substantially concave outer surface (concave surfaces 19, 21) capable of seating (see Figure 3) a graft member (ligaments 100), and each sidewall being at least partially separated by a longitudinally oriented opening (described as a "slit"; see Figures; see entire document) extending from a proximal end (proximal end 14) along a substantial length of each sidewall and terminating at a position just proximal to the distal tip; and (ii) a bioabsorbable (see paragraphs 0040, 0050) sheath expander (anchor screw 72 or wedge 48) capable of being disposed in the central lumen of the radially expandable sheath, and capable of flexing the sidewalls of the radially expandable sheath (see paragraphs 0037-0042 and paragraph 0053). The bioabsorbable radially expandable sheath further includes surface features (ridges/barbs 24, 26) that may act as stop members.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 11-13 and 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beck, Jr. et al. (US 5,632,748 A).

Referring to Figures 9 and 10, Beck, Jr. et al. disclose a graft fixation device comprising: (i) a bioabsorbable (see column 13, lines 25-40) radially expandable (see column 14, lines 39-54) sheath (endosteal anchor member 416) having a slot-free distal tip (tip 421) with at least two sidewalls (wings 52) extending proximally therefrom and defining a central lumen (canal 50), each sidewall being at least partially separated by a longitudinally oriented opening (see Figures 9 and 10) extending from a proximal end along a substantial length of each sidewall and terminating at a position just proximal to the distal tip; and (ii) a sheath expander (insertion member 28) capable of being disposed in the central lumen of the radially expandable sheath, and capable of flexing the sidewalls of the radially expandable sheath (see column 14, lines 39-54). The bioabsorbable radially expandable sheath further includes surface features (urging members 40), and a stop member (extended portions of wings 52) at a proximal end.

Although Beck, Jr. et al. teach (see column 14, lines 21-23) insertion member 28 as “comprised of metal or any other suitable material”, they did not particularly disclose said material as a “biodegradable” material. However, this is well known in the art. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have used a biodegradable expander with the invention of Beck, Jr. et al., since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

8. Claims 1-3, 11-13, 20, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Strobel et al. (US 2001/0007074 A1).

Referring to Figures 1, 3, 4, 8, and 9, Strobel et al. disclose a graft fixation device (anchor 10) comprising: (i) a bioabsorbable (see paragraph 0040) sheath having a slot-free distal tip (penetration end 18) with at least two sidewalls (Figures 3 and 4: sidewalls 12) extending proximally therefrom and defining a central lumen (central channel 33), each sidewall having a substantially concave outer surface (recesses 26 in the form of axially disposed grooves 28, or, the concave surfaces defined by threading 22) capable of seating a graft member (ligament 102), and each sidewall being at least partially separated by a longitudinally oriented opening (openings 34'), as a whole, define a "longitudinally oriented opening") extending from a proximal end along a substantial length of each sidewall and terminating at a position just proximal to the distal tip; and (ii) a sheath expander (pin 94 or bridge 78) capable of being disposed in the central lumen of the radially expandable sheath, and capable of flexing the sidewalls of the radially expandable sheath.

Strobel et al. did not particularly disclose the material of the expander as a "biodegradable" material. However, this is well known in the art. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have used a biodegradable expander with the invention of Strobel et al., since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Note: Claims directed to apparatus must be distinguished from the prior art in terms of structure rather than function. *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA 1959).

"[A]pparatus claims cover what a device is, not what a device does." *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990).

Expressions relating the apparatus to contents thereof during an intended operation are of no significance in determining patentability of the apparatus claim. *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969).

9. Claims 1-4, 8, 9, 11-14, 20, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jacobs et al. (WO 02/32345 A2; cited in Applicants' IDS).

Referring to Figures 1A, 2B, 3, 5A, and 5B, Jacobs et al. discloses a graft fixation device comprising: (i) a bioabsorbable (see page 3, lines 11-14; page 7, lines 9-24) radially expandable sheath (Figure 5A: device 190) having a slot-free distal tip (Figure 3: distal tip) with at least two sidewalls (Figure 5A: spring arms 192, 194, 198, and 200) extending proximally therefrom and defining a central lumen (Figure 5A: central lumen and/or passageway 178), each sidewall having a substantially concave outer surface (exterior cavity 196) capable of seating a graft member, and each sidewall being at least partially separated by a longitudinally oriented opening (Figure 5A: longitudinally oriented openings between spring arms 192, 194, 198, and 200) extending from a proximal end along a substantial length of each sidewall and terminating at a position just proximal to the distal tip. The substantially concave outer surfaces include surface features (Figure 5A: barbs 204). The sheath further includes stop members (Figure 5A: protuberances 202). Passageway 178 is capable of receiving a guidewire if one skilled in the art desires so.

With regards to the "bioabsorbable sheath expander", it is noted that the claim language does not recite structure defining said "bioabsorbable sheath expander", so the Examiner is broadly

interpreting said “expander” as the tool (e.g., Figure 4D: pin 184), instrument, or wedge used to implant/manipulate the bioabsorbable radially expandable sheath. Said tool, instrument, screw, and/or wedge are well known in the art, and is capable of being disposed in the central lumen of the radially expandable sheath, and capable of flexing the sidewalls of the radially expandable sheath if one skilled in the art desires so.

Jacobs et al. did not particularly disclose the material of the expander as a “biodegradable” material. However, this is well known in the art. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have used a biodegradable expander with the invention of Jacobs et al., since it has been held to be within the general skill of a worker in the art to select a know material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Note: Claims directed to apparatus must be distinguished from the prior art in terms of structure rather than function. *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA 1959).

“[A]pparatus claims cover what a device is, not what a device does.” *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990).

Expressions relating the apparatus to contents thereof during an intended operation are of no significance in determining patentability of the apparatus claim. *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969)

10. Claims 5-7 and 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jacobs et al. (WO 02/32345 A2; cited in Applicants’ IDS) in view of Hays et al. (US 2002/0072797 A1).

With regards to claims 5 and 15, Jacobs et al. disclose the invention as claimed in claims 1-4, 8, 11-14, 20, and 21, except for particularly disclosing a stop member at a proximal end of the sheath. However, this is already known in the art. For example, Hays et al. disclose stop members 1000 at a proximal end of sheath 400 in order to prevent over-insertion of the sheath into a bone tunnel (see entire document). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to have combined the teaching of adding stop members at a proximal end of an expandable sheath, as taught by Hays et al. (US 2002/0072797 A1), with the invention of Jacobs et al., in order to prevent over-insertion of said sheath into a bone tunnel.

With regards to claims 6, 7, 16, and 17, Jacobs et al. disclose the invention as claimed in claims 1-4, 8, 11-14, 20, and 21, except for particularly disclosing the expander as a tapered screw. However, this is already known in the art. For example, Hays et al. disclose sheath expanders (such as tapered screw sheath expander 700) as insertable into central lumen 450 of expandable sheath 400 in order to deform or expand the sidewalls of said sheath. Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to have combined the teaching of using a tapered screw as a sheath expander, as taught by Hays et al. (US 2002/0072797 A1), with the invention of Jacobs et al., in order to deform or expand the sidewalls of said sheath with said tapered screw.

Response to Arguments

11. Applicant's arguments with respect to claims 1 and 11 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Javier G. Blanco whose telephone number is 571-272-4747. The examiner can normally be reached on M-F (9:30 a.m.-7:00 p.m.), first Friday of the bi-week off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone numbers for the organization where this application or proceeding is assigned is 703-872-9306 for regular communications and After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

JGB

August 23, 2006



David H. Willse
Primary Examiner